K012768

SEP 1 8 2001

Section 3
HemosIL RecombiPlasTin - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4464

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

August 16, 2001

Name of the Device:

HemosIL RecombiPlasTin

Classification Name(s):

864.7750	Prothrombin Time Test	Class II
81GJS	Test, Time, Prothrombin	
864.7340	Fibrinogen Determination System	Class II
81GIS	Test, Fibrinogen	

Identification of Predicate Device(s):

K925604 Hemoliance® RecombiPlasTin (PT Claims for IL Coagulation and ELECTRA Systems)

K862301 IL Test™ PT-Fibrinogen (Fibrinogen Claims for IL Coagulation Systems Only)

Description of the Device/Intended Use(s):

A high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the *in vitro* diagnostic quantitative determination in human citrated plasma of:

- Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems
- Fibrinogen on IL Coagulation Systems only

The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL RecombiPlasTin is substantially equivalent to Hemoliance® RecombiPlasTin (for Prothrombin Time on IL Coagulation and ELECTRA Systems) and IL Test™ PT-Fibrinogen (for Fibrinogen on IL Coagulation Systems only) in performance, intended use and safety and effectiveness.

Section 3
HemosIL RecombiPlasTin - 510(k) Summary
(Summary of Safety and Effectiveness)

Summary of Performance Data:

Method Comparison

In method comparison studies evaluating 180 citrated plasma samples (100 normal donors and 80 abnormal patient samples) on an ACL 3000, ACL Futura and ELECTRA 1400C, the slopes and correlation coefficients (r) for HemosIL RecombiPlasTin versus the predicate devices are shown below:

Prothrombin Time (seconds) on IL Coagulation and ELECTRA Systems:

New Device vs. Predicate Device for PT: Hemoliance® RecombiPlasTin

IL System	Slope	r
ACL 9000	0.90	0.993
ACL Futura	0.99	0.995
E1400C	0.95	0.996

Fibrinogen (mg/dL) on IL Coagulation Systems Only:

New Device vs. Predicate Device for Fib: IL Test™ PT-Fibrinogen*

IL System	Slope	r
ACL 9000	1.00	0.933
ACL Futura	1.10	0.957

***NOTE:** Values outside the linearity claim of 700 mg/dL were removed from calculations for a respective n=164 on the ACL 9000 and n=170 on the ACL Futura.

Within Run Precision

Within run precision assessed over multiple runs using three levels for Prothrombin Time and two levels for Fibrinogen of control plasmas gave the following results:

		PT (seconds)		Fibrinogen (mg/dL)	
ACL 9000	**Level 1**	**Level II**	**Level III**	**Level 1**	**Low Fibrinogen**
Mean	11.8	28.8	57.1	303	127
% CV	0.8	2.5	1.7	4.3	3.6

		PT (seconds)		Fibrinogen (mg/dL)	
ACL Futura	**Level 1**	**Level II**	**Level III**	**Level 1**	**Low Fibrinogen**
Mean	11.0	30.4	61.6	261	119
% CV	1.1	1.2	1.1	4.5	9.8

		PT (seconds)	
E1400C	**Level 1**	**Level II**	**Level III**
Mean	12.3	29.0	57.8
% CV	0.9	1.9	2.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K012768
Trade Name: HemosIL RecombiPlasTin
Regulation Number: 21 CFR § 864.7750 and 21 CFR § 864.7340
Regulatory Class: II
Product Code: GJS, GGP, GIS
Dated: August 16, 2001
Received: August 17, 2001

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012768

Device Name: HemosIL RecombiPlasTin

Indications for Use:

A high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the quantitative *in vitro* diagnostic determination in human citrated plasma of:

- Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems
- Fibrinogen on IL Coagulation Systems only

The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012768

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)